Exhibit 8
(Filed Under Seal)

Report on the Bard Inferior Vena Cava Filter Implanted in Mrs. Debra Tinlin

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This report supplements my general reports dated March 3, 2017, April 7, 2017, April 21, 2017, and May 12, 2017, previously served in this litigation concerning Bard inferior vena cava filters, and I incorporate my previous reports into the present one. I also include all the references in those reports in my reliance list. The purpose of the present report is to provide my opinions and findings regarding the Bard Recovery filter implanted in Mrs. Debra Tinlin.

I provide a true and correct copy of my curriculum vitae attached as Exhibit A.

My billing rate is $400 per hour for consulting work and $800 per hour for deposition and court testimony. My prior testimony in the past 4 years is listed in an appendix.

My opinions in this report are to a reasonable degree of scientific and engineering certainty.

Mrs. Debra Tinlin's filter

I have been provided and reviewed medical records pertaining to Debra Tinlin, as well as the expert reports of Dr. Darren Hurst and Dr. Derek Muehrcke. Based on my review of that information, it is my understanding that:

- On May 7, 2005, Mrs. Tinlin had a Bard Recovery inferior vena cava filter placed with no significant tilt.

- On May 8, 2005, the filter is identified as having 18° of tilt with its tip against the anterior wall of the IVC and with caudal migration of 9 mm. All 6 of its arms and 2 of its legs are identified as having penetrated the wall of the IVC.

- The filter subsequently fractured, and the fractured arm embolized to the right ventricle. Thereafter a 2nd arm fractured and embolized to the right ventricle.

- By June 11, 2007, the filter is identified as having experienced further caudal migration and to be experiencing splaying of a right arm.

- Subsequently a 3rd arm fractured and embolized to the pulmonary artery.

- By February 3, 2012, the filter had experienced caudal migration by 2.8 cm and a 4th arm had fractured and embolized to the pulmonary artery.

- Subsequently a 5th arm fractured and embolized to the pulmonary artery.

- On July 30, 2013, Mrs. Tinlin underwent open heart surgery during which 1 fractured filter arm was removed successfully, but the other fractured filter arm in her heart could not be found.

- Mrs. Tinlin's filter migrated, tilted, perforated and fractured, with pieces of the fractured arms remaining within her. The body of the filter is still in her IVC.

- Mrs. Tinlin's Recovery filter was used as intended, properly implanted, and there were no other causes of the failures of that filter.

Based upon my review of the referenced medical records and expert reports, and consistent with my evaluation of the Bard Recovery filter and my opinions regarding failure modes of the Recovery filter, I have determined to a reasonable degree of engineering and scientific certainty that Mrs. Tinlin's Recovery filter experienced all of the failure modes consistent with the defects inherent in the Recovery filter. The Recovery filter has significant problems relating to migration (including caudal migration), tilt, perforation, and fracture, and peer reviewed articles in the medical and scientific literature support and confirm my assessment [1-9]. Mrs. Tinlin's filter failed in all of those ways.

Bard made a choice to design the Recovery filter without caudal anchors or other features that would prevent and/or minimize caudal migration. Caudal migration is often associated with tilt which occurs when the axis of the conical profile of the filter is not parallel with the axis of the vena cava. Caudal migration can cause tilt and tilt can cause caudal migration. In my opinion, Mrs. Tinlin's Recovery filter likely migrated caudally and tilted due to the design defects of the Recovery filter.

Bard made a choice to design the Recovery filter without perforation limiters or other features that would prevent and/or minimize perforation of the filter limbs through the walls of the IVC. Perforation of the limbs through the wall of the IVC is made more likely by tilt because of the way that the sharp, thin, needle-like limbs of a tilted filter interact with and cut through the wall of the IVC. Tilt is also made more likely by limbs of the filter perforating the wall of the IVC. In my opinion, Mrs. Tinlin's filter likely tilted and perforated the wall of the IVC due to the design defects of the Recovery filter.

Bard made a choice to design the Recovery filter without features that would prevent and/or minimize tilt, or that would limit the negative consequences of tilt. Tilt is an instability of the Recovery filter that is associated with its improper design. Tilt is often associated with caudal migration. Perforation of the limbs through the wall of the IVC is made more likely by tilt because of the way that the sharp limbs of a tilted filter interact with and cut through the wall of the IVC. Tilt is also made more likely by limb perforation.

Tilt and perforation are, in turn, associated with the greater likelihood of filter fracture due to fatigue. Fractures caused by fatigue damage to the Nitinol (the material the Bard Recovery filter is made of) result from cyclic loading. Repeated changes to the vena cava cross sectional dimensions and/or impact of successive clots trapped by the filter cause cyclic loading and the

resulting fatigue damage and fracture risk. As described in my main MDL reports, both tilt and perforation increase the severity of the effect of the cyclic loading that filters experience in the IVC. Observations and findings of fatigue damage leading to fractures of Recovery filters are described in reports of Dr. Robert O. Ritchie, NAE, FREng, FRS. Respiration and Valsalva maneuvers can cause fatigue damage that can compromise the filter by fracturing its limbs. Valsalva maneuvers can also compromise the filter by causing permanent deformation that misshapes it. Both limb fracture and permanent deformation can cause the filter to be an inefficient clot-trapping device. As I have concluded in other reports, perforation and tilt increase the probability of fracture by fatigue.

All of the design failures discussed above would have been known to a reasonably prudent engineer when the Recovery filter was being designed and tested and prior to when it was implanted in Mrs. Tinlin, and were foreseeable to Bard. A reasonably prudent engineer could have incorporated design features that were known in the field prior to when Mrs. Tinlin received her filter, and incorporation of these features would have helped to mitigate or eliminate the failures I have identified and that occurred in Mrs. Tinlin's filter. Specifically, reasonable alternative designs and alternative features available to Bard before Mrs. Tinlin received her filter include many features that I have previously identified in my reports and deposition testimony: caudal anchors, penetration limiters, two-tier design, and a better (smoother and rounded) chamfer at the mouth of the "cap" on the filter. Many of these design features existed in other IVC filter products already on the market, including the Simon Nitinol Filter, the Cook Gunther Tulip filter [10], the Greenfield filter [11], and the Cook Bird's Nest filter [12].

Bard made a choice to design, manufacture and market the Recovery filter without adequate bench testing and without adequate stress and strain analysis. The bench tests that Bard carried out on the Recovery filter were inadequate in that they did not implement conditions in the test to invoke reasonably foreseeable worst-case conditions. For example, as summarized in the 510 (K) application for the Recovery [13], in the fatigue tests of the Recovery filter Bard did not test filters in conditions representative of tilt, limb perforation and endothelialization, and did not test for 10 years of respiration at worst-case (or even typical) rates of breathing. The FDA document, *Guidance for Cardiovascular Intravascular Filter 510(k) Submissions* [14] states on page 4 that "The filter's response to worst-case respiratory and diaphragmatic movements in the vena cava under simulated respiratory cycles should demonstrate sufficient fatigue resistance of the filter design." Taking foreseeable worst-case conditions into account, designing for them and testing for them is fundamental to adequate engineering design. Bard's investigations of the conditions implanted filters would experience that could cause them to fracture due to cyclic fatigue was insufficient and did not conform to what is expected of a prudent engineer.

Further, the device failures experienced by Mrs. Tinlin's Recovery filter are directly attributable to Bard's failure to adequately test the Recovery filter in its bench testing prior to marketing and selling the device into the market and specifically to Mrs. Tinlin's implanting physician. Bard failed to carry out necessary tests to address the likelihood of limb perforation and tilt [13]. Bard made no attempt and/or insufficient attempts to determine the conditions that implanted filters would experience that could cause them to perforate the wall of the IVC and/or tilt [13]. As a result of Bard's failure to test for these known potential complications of IVC filters, Bard failed

to reasonably design the Recovery to avoid them. As a result of that failure, Mrs. Tinlin's filter tilted significantly and its struts perforated her IVC.

The bench tests that Bard actually did conduct failed to account for these conditions – tilt and perforation – or to account for reasonably foreseeable worst-case conditions for the filter [13]. The bench tests addressing migration that Bard carried out on the Recovery filter were inadequate in that Bard made no attempt and/or insufficient attempts to determine the conditions that implanted filters would experience that could cause them to migrate. Bard failed to conduct reasonable migration testing of the Recovery and that testing used a standard (50 mmHg) that was not reasonably related to an objective measure of reasonable migration resistance [13]. Further, Bard's migration testing demonstrated that the Recovery failed even Bard's required standard of migration resistance [21, 22]. Bard's testing was further predominantly comparative testing and demonstrated that the Recovery was significantly less migration resistant than the SNF and virtually all of the competing IVC filters on the market [21, 22]. And, Bard failed to conduct caudal migration resistance testing for the Recovery. Had Bard engaged in proper migration-resistance testing of the Recovery, it would have determined that the device was not sufficiently resistant to migration and designed the device differently to account for the lack of such resistance. Indeed, Mr. DeCant, Bard's Vice Present of Research and Development, testified that by approximately April 2004, Bard was aware that the Recovery filter was not designed to account for how the vena cava actually behaved [23]. Due to these failures, Mrs. Tinlin's Recovery filter migrated after implantation.

In addition, the stress and strain analysis that Bard carried out for the Recovery filter was inadequate, inaccurate, and incomplete. Bard failed to conduct reasonable testing of the Recovery filter's fatigue and fracture resistance. As discussed in my other reports, Bard's fatigue testing was inadequate because it failed to account for worst-case scenario and instead assumed the best case situation of the filter being perfectly centered, not perforating, and not tilting within the IVC. Thus, its testing did not adequately or accurately measure how the filter would perform in more strenuous conditions in the IVC [15, 16, 17]. This is particularly important to the fracture of Mrs. Tinlin's Recovery filter, as it was tilted, off-center, and had significant perforations at the time of its various fractures. In fact, Bard's Recovery arm fatigue resistance test (BPVE-17-01-00000781) demonstrates that Bard was aware, well before Mrs. Tinlin's implant date for the Recovery filter, that the Recovery was prone to circumstances upon implantation that were likely to cause it to fracture early and often. Had Bard appropriately tested the Recovery for fatigue and fracture resistance, it would have known that the Recovery was very likely to fracture when implanted in patients and would have designed the device differently to account for those problems. Due to those testing failures, Mrs. Tinlin's Recovery filter fractured multiple times.

In the case of Mrs. Tinlin's Recovery filter, the reports by Dr. Hurst and Dr. Muehrcke indicates to me that its failure modes probably began with tilt, caudal migration and arm perforation. These in turn caused fractures of arms that embolized to Mrs. Tinlin's right ventricle and right pulmonary artery. As I have concluded in other assessments, and based upon my own investigations and calculations, filter arm fracture due to cyclic loading resulted in pieces of arms breaking loose from the filter. Bard made the choice to design the filter in such a way that it lacked redundancy so that if a limb fractured due to fatigue the broken end would embolize in the cardiovascular and

pulmonary system. All of these failures are caused by the improper design of the Recovery filter that made it an unreasonably dangerous device.

In summary, the failures of Mrs. Tinlin's Recovery filter are consistent with the kind of failures associated with that filter, occurred in the manner detailed herein and in my previous general reports, and are consequences of the improper and inadequate design of the Bard Recovery filter as detailed in my previous reports and herein. The Bard Recovery filter is improperly and inadequately designed such that it does not prevent tilt, caudal migration, fracture, and perforation, as it lacks adequate safeguards against these failure modes. To a reasonable degree of scientific and engineering probability and certainty, the failures of Mrs. Tinlin's Recovery IVC filter resulted from poor design, inadequate testing prior to marketing the filter and implantation of the filter in Mrs. Tinlin, and improper internal assessment of the filter via analysis, including finite element analysis and other methods of analysis, as set forth specifically and completely in my previous reports in this Bard IVC filter litigation and incorporated herein.

By the time Mrs. Tinlin had her Recovery filter implanted in her in 2005 the Recovery filter was experiencing failures by tilt, migration, perforation and fatigue fracture and Bard was aware of these failures. In my opinion, Bard should have been able to identify the root causes of the Recovery failures based on adequate testing and design and engineering principles, and taken the Recovery filter off the market once it was aware of the failures the Recovery filter was experiencing. Bard conducted "root-cause" analyses but was never able to ascertain a cause for the failures. Thus, it neither determined what was causing the Recovery filter failures nor eliminated the device's design as the cause of the failures. Bard should have carried out a complete root-cause analysis to determine the causes of those failures and redesigned the Recovery to reduce or eliminate those failures to the extent possible before implanting the Recovery filter in additional patients. The root-cause analysis that Bard should have carried out would have included a thorough assessment of the environment and conditions that implanted filters would experience, a thorough and accurate strain and stress analysis of the filter, including proper assessments of its possible failure modes, and thorough bench testing of the filter in setups that represented foreseeable worst-case conditions that the filter would experience. With respect to the specific environment of use of Mrs. Tinlin's filter, with struts abutting the vertebral body, Bard should have foreseen this potential condition of a rigid and fixed exterior surface and included this scenario in its bench testing and strain and stress analysis. It is my opinion that Bard failed to carry out such a root cause analysis, and that by failing to do so Bard put patients at risk of injury due to, *inter alia*, not determining how to redesign the Recovery filter to reduce or eliminate the failures it was experiencing. The absence of such a root-cause analysis is confirmed by the continued failures experienced by the redesigned G2 filter, with my assessment of this supported and confirmed by articles in the scientific literature [2, 4, 5, 6, 8, 9, 18, 19, 20].

Both in this failure to carry out a root cause analysis and in their actions when designing the Recovery filter, Bard failed to follow the standards of safe and reliable design. As patient safety is paramount, engineers and companies designing medical implants must identify the conditions and environment that the device will experience after implantation, must identify the devices potential problems and failure modes, must test for them, and must design to eliminate or reduce failure modes as much as possible. Bard failed to follow these principles and as a consequence their design of the Recovery filter was inadequate.

To the extent Mrs. Tinlin's fractured filter body and limbs are removed at some point while this litigation is pending (which is not expected), I reserve the right to examine those fragments and supplement my opinions. Additionally, I understand that discovery is ongoing, and reserve the right to supplement/amend my opinions if additional pertinent/relevant information is obtained.

References

[1] S.P. Kalva, C.A. Athanasoulis, C.-M. Fan, M. Curvelo, S.C. Geller, A.J. Greenfield, A.C. Waltman and S. Wicky, "'Recovery™' Vena Cava Filter: Experience in 96 Patients," *CardioVascular and Interventional Radiology*, Vol. 29, pp. 559-564 (2006).

[2] A. Berczi, J.R. Bottomley, S.M. Thomas, S. Taneja and P.A. Gaines, "Long-Term Retrievability of IVC Filters: Should We Abandon Permanent Devices," *CardioVascular and Interventional Radiology*, Vol. 30, pp. 820-827 (2007).

[3] J.E. Hull and S.W. Robertson, "Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration," *Journal of Vascular and Interventional Radiology*, Vol. 20, pp. 52-60 (2009).

[4] C.P. Cantwell, J. Pennypacker, H. Singh, L.B. Scorza, P.N. Waybill and F.C. Lynch, "Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters," *Journal of Vascular and Interventional Radiology*, Vol. 20, pp. 1193-1199 (2009).

[5] W. Nicholson, W.J. Nicholson, P. Tolerico, B. Taylor, S. Solomon, T. Schryver, K. McCullum, H. Goldberg, J. Mills, B. Schuler, L. Shears, L. Siddoway, N. Agarwal and C. Tuohy, "Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade," *Archives of Internal Medicine*, Vol. 170, pp. 1827-1831 (2010).

[6] K. Vijay, J.A. Hughes, A.S. Burdette, L.B. Scorza, H. Singh, P.N. Waybill and F.C. Lynch, "Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts," *Journal of Vascular and Interventional Radiology*, Vol. 23, pp. 188-194 (2012).

[7] M.D. Tam, J. Spain, M. Lieber, M. Geisinger, M.J. Sands and W. Wang, "Fracture and Distant Migration of the Bard Recovery Filter: A Retrospective Review of 363 Implantations for Potentially Life-Threatening Complications," *Journal of Vascular and Interventional Radiology*, Vol. 23, pp. 199-205 (2012).

[8] S.E. Deso, I.A. Idakoji and W.T. Kuo, "Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type," *Seminars in Interventional Radiology*, Vol. 33, pp. 93-100 (2016).

[9] A.J. Kesselman, N.S. Hoang, A.Y. Sheu and W.T. Kuo, "Endovascular Removal of Fractured Inferior Vena Cava Filter Fragments: 5-Year Registry Data with Prospective Outcomes on Retained Fragments," *Journal of Vascular and Interventional Radiology*, Vol. 29, pp. 758-764 (2018).

[10] J. Neuerburg, R.W. Günther, E. Rassmussen, D. Vorwerk, K. Tonn, S. Handt, W. Küpper and J. Vagn Hansen, "New Retrievable Percutaneous Vena Cava Filter: Experimental *In Vivo* and *In Vitro* Examination," *Cardiovascular and Interventional Radiology*, Vol. 16, pp. 224-229 (1993).

[11] L.J. Greenfield, K.J. Cho and J.R. Tauscher, "Evolution of the hook Design for Fixation of the Titanium Greenfield Filter," *Journal of Vascular Surgery*, Vol. 12, pp. 345-353 (1990).

[12] J. Roehm, Jnr., "The Bird's Nest Filter: A New Percutaneous Transcatheter Inferior Vena Cava Filter," *Journal of Vascular Surgery*, Vol. 1, pp. 498-501 (1984).

[13] 11/1/1999 Special 510(k) Submission for Recovery Filter (BPV-17-01-00002677-BPV-17-01-00002780); Complete Special 510(k): Device Modification submission for the Recovery Filter System, submitted 7/8/2002 (BPV-DEP-00004287-BPV-DEP-00004316).

[14] *Guidance for Industry and FDA Reviewers/Staff: Guidance for Cardiovascular Intravascular Filter 510(k) Submissions*, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Interventional Cardiology Devices Branch, Division of Cardiovascular and Respiratory Devices, Office of Device Evaluation. Document issued on: November 26, 1999.

[15] E.H. Murphy, E.D. Johnson and F.R. Arko, "Evaluation of Wall Motion and Dynamic Geometry of the Inferior Vena Cava Using Intravascular Ultrasound: Implications for Future Device Design," *Journal of Endovascular Therapy* Vol. 15, pp. 349-355 (2008).

[16] A. Laborda, S. Sierre, M. Malvè, I. De Blas, I. Ioakeim and W.T. Kuo, "Influence of Breathing Movements and Valsalva Maneuver on Vena Caval Dynamics," *World Journal of Radiology* Vol. 6, Issue 10, pp. 833-839 (2014).

[17] A. Laborda, W.T. Kuo, I. Ioakeim, I. De Blas, M. Malve, C. Lahuerta and M.A. De Gregorio, "Respiratory-Induced Haemodynamic Changes: A Contributing Factor to IV Filter Penetration," *Cardiovascular and Interventional Radiology*, Vol. 38, No. 5, pp. 1192-1197 (2015).

[18] V.L. Oliva, P. Perrault, M.-F. Giroux, L. Bouchard, E. Therasse and G. Soulez, "Recovery G2 Inferior Vena Cava Filter Success and Safety of Retrieval," *Journal of Vascular and Interventional Radiology*, Vol. 19, pp. 884-889 (2008).

[19] F.C. Lynch and S. Kekulawela, "Removal of the G2 Filter: Differences between Implantation Times greater and Less then 180 Days," *Journal of Vascular and Interventional Radiology*, Vol. 20, pp. 1200-1209 (2009).

[20] C.A. Binkert, A.T. Drooz, J.C. Caridi, M.J. Sands, H. Bjarnason, F.C. Lynch, W.S. Rilling, D.Z. Zambuto, S.V. Stavropouls, A.C. Venbrux and J.A. Kaufman, "Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study," *Journal of Vascular and Interventional Radiology*, Vol. 20, pp. 1449-1453 (2009).

[21] Engineering Test Report ETR-04-03-02, Characterization of Recovery Filter Migration Resistance in Comparison to Competitive Product, BPVE-01-00276094-6106, at pp. 3-6.

[22] Email from Alex Tessmer to Robert Carr and Brian Hudson, dated Feb. 25, 2004, re Filter Migration Test Results, BPVE-01-00410985, and attached spreadsheets demonstrating test results.

[23] Deposition of Len DeCant, dated May 24, 2016, at 329:2-8.

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